

Notice from the Executive Officer: Supporting Sustainability and Access for the Ontario Drug Benefit Program

Responsible management of health care is part of the government's plan to build a better Ontario through its [Patients First: Action Plan for Health Care](#), providing patients with faster access to the right care, better home and community care, the information they need to live healthy and a health care system that's sustainable for generations to come.

The Ministry of Health and Long-Term Care (the "ministry") is making changes to pharmacy payments, fees and program policies under the Ontario Drug Benefit (ODB) program to make the program more efficient, effective and responsive to today's patients.

These initiatives represent a fair and balanced approach to generating savings and will contribute to the Province's efforts to identify short- and longer-term opportunities that will ensure continued patient access to drugs. These changes will enable the government to achieve savings of over \$200 million annually when fully implemented, as per the 2015 Ontario Budget.

Amendments to Ontario Regulation 201/96 made under the *Ontario Drug Benefit* will come into force on October 1, 2015 to support these ODB program changes. All initiatives will be enforced in the manner outlined below.

1. Mark-up Reduction for High-Cost Drugs

The ministry reimburses the pharmacy for the Drug Benefit Price as listed on the ODB Formulary in respect of each claim plus the mark-up on that amount.

Effective October 1, 2015, the mark-up for all ODB claims for high-cost drugs (total drug cost equal to or greater than \$1000) will be reduced from 8% to 6%.

Claims for prescriptions with total drug costs less than \$1000 will continue to be reimbursed with 8% mark-up.

Pharmacists are expected to dispense quantities as directed by the prescriber. All claims will continue to be subject to audit and recovery.

2. Dispensing Fee Reduction for Claims for Residents of Long-Term Care Homes

Effective October 1, 2015, the ministry is reducing the ODB dispensing fee paid to pharmacies for claims for residents of Long-Term Care Homes (LTCH) by \$1.26 across all categories of pharmacies, including hospital outpatient dispensing pharmacies and community pharmacies in rural and remote areas. Table 1 below outlines the reduced ODB dispensing fees.

Table 1: Dispensing fees for claims for Long-Term Care Home residents

Accredited Pharmacy Type	ODB Dispensing Fee effective Oct 1, 2015 (\$1.26 reduction)
For most pharmacies	\$7.57
When there is only one pharmacy within 5kms, OR When the nearest pharmacy is within 5 to 10 kms	\$8.67
When the nearest pharmacy is within 10 to 25kms	\$10.88
When there are no other pharmacies within 25kms	\$11.99
Hospital outpatient pharmacy	\$7.57

3. Maximizing the Quantity Dispensed for Chronic-Use Medications

Effective October 1, 2015, the ministry is limiting the number of dispensing fees paid to pharmacies for 15 categories of chronic-use medications, to a maximum of **five (5)** dispensing fees per recipient, per drug (by interchangeable category), per 365-day period. The 15 categories of chronic-use medications are listed in Table 2 below.

Where the maximum number of dispensing fees per year per patient per chronic-use drug has been reached, the Ministry will only reimburse the pharmacy for the Drug Benefit Price as listed on the ODB Formulary in respect of each claim plus the applicable mark-up on that amount.

The conditions for payment of a dispensing fee for chronic-use medications will apply to Trillium recipients once they have reached their deductible. Only claims submitted after the deductible has been met will be counted towards the 5 fee per year limit.

Table 2: Chronic-use medications list

Chronic-Use Drug Category	ODB Drug Product Examples*
ACE Inhibitors	Enalapril, ramipril, quinapril
Angiotensin II Receptor Blockers	Candesartan, irbesartan, valsartan
Beta-Blockers	Atenolol, metoprolol, sotalol
Calcium Channel Blockers	Amlodipine, diltiazem, nifedipine
Other Drugs Used for Hypertension	Methyldopa, prazosin, terazosin
Other Cardiac Drugs	Amiodarone, digoxin, isosorbide, pentoxifylline
Statin Drugs Used to Lower Cholesterol	Atorvastatin, lovastatin, rosuvastatin
Other Drugs Used to Lower Cholesterol	Bezafibrate, ezetimibe, gemfibrozil
Oral Anti-diabetic Agents	Glyburide, metformin, saxagliptin

Chronic-Use Drug Category	ODB Drug Product Examples*
Diuretics	Furosemide, hydrochlorothiazide, indapamide
Drugs Used for GI Conditions	Famotidine, misoprostol, omeprazole, sucralfate
Drugs Used to Prevent Gout	Allopurinol
Oral Iron Replacement Therapy	Ferrous fumarate, ferrous gluconate
Drugs Used for Osteoporosis	Alendronate, raloxifene, risedronate
Drugs Used for Prostate Conditions	Dutasteride, silodosin, tamsulosin

*List is not exhaustive

The full list of medications that fall under the 15 categories of chronic-use medications that are subject to the 5 dispensing fees per 365-day period rule is posted on the ministry website at: http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/eo_communiq.aspx. This list will be updated on an as-needed basis.

Exemptions

The conditions for payment of a dispensing fee for chronic-use medications do not apply to Ontario Works (OW) recipients, LTCH residents and residents of publicly-funded residential care facilities listed on the ministry's website (i.e. Homes for Special Care). All extemporaneous preparations of chronic-use medications are also exempt from this change.

ODB recipients who require more frequent dispensing due to an established physical, cognitive or sensory impairment, or because they are on a complex medication regimen where their safety is at risk, can continue to receive their chronic-use medications at more frequent intervals.

Where the dispenser has determined, in his or her professional opinion, that the ODB recipient is incapable of managing his/her medication regimen as a result of physical, cognitive or sensory impairment or a complex medication regimen where the recipient's safety is at risk, the dispenser is required to notify the prescriber with the rationale for the decision.

Documentation must include the reason for this opinion, the dispenser's notification to the prescriber, as well as a record of the authorization received from the ODB recipient (or person presenting the prescription) for dispensing in reduced quantities. The nature of the physical, cognitive or sensory impairment or complex medication regimen must be clearly documented, including clinical or safety risks to the patient if larger quantities were dispensed.

These authorizations are valid for a period of 365 days and are required to be updated annually, and maintained as part of the ODB recipient's permanent pharmacy health record.

ODB recipients who are deemed to require more frequent dispensing will need to be assessed regularly to verify an ongoing need for more frequent dispensing. For example, a patient on a complex medication regimen may require assistance for a short period of time, in order to learn

to manage their medications as directed, but once stabilized, may be capable of managing 100 day supplies.

The ministry has also amended O. Reg. 201/96 made under the ODBA to clarify that the co-payment for ODB recipients may only be charged when the dispenser is eligible to receive a dispensing fee from the ministry. Therefore, once the 5 fee/year limit for a chronic-use medication has been reached, the ODB-eligible recipient cannot be charged the co-payment or any unpaid fee amount for further dispensing transactions. Although claims submitted in excess of the annual 5 fee limit for chronic-use medications are not eligible for payment of a dispensing fee, dispensers will still receive payment for the drug benefit price plus any applicable markup. Pharmacists are encouraged to work with prescribers and patients to facilitate the dispensing of 100 day supplies for chronic-use medications.

It is anticipated that Health Network System (HNS) changes will be implemented mid-2016, and at that time, **patient profiles will be reviewed back to October 1, 2015. Where 5 dispensing fees have been paid for a chronic-use medication, pharmacies will not be entitled to receive additional fees for 365 days after the first claim for that chronic-use medication.** Until the HNS changes are implemented in 2016, it will be the responsibility of pharmacists and pharmacy staff to ensure their dispensing practices are in compliance with this initiative. All claims will be subject to audit review and recovery.

4. Reimbursement of Medically Necessary “No Substitution” Claims

The ministry is changing the current “no substitution” policy in order to enhance the use of safe and effective generic alternatives to brand name products. Health Canada has stringent regulations in place to ensure only safe and effective products are marketed, regardless of whether they are brand or generic drugs.

Effective October 1, 2015, the ministry will reimburse a higher-cost brand product through a “no substitution” claim in medically necessary circumstances where an ODB recipient has experienced a significant adverse reaction to a minimum of **two (2)** interchangeable generic drug products, where two or more interchangeable generic products are listed on the ODB Formulary/Comparative Drug Index (Formulary).

Where only one interchangeable generic product is listed as a benefit, the ministry will reimburse the higher-cost brand product, provided the ODB recipient has tried the listed generic product and has experienced a significant adverse reaction.

Prescribers are required to complete, sign and forward to the pharmacist a copy of the Health Canada [Canada Vigilance Adverse Reaction Reporting Form](#) for **each** lower-cost interchangeable drug product trialed, and will continue to be required to write “no substitution” or “no sub” on a written prescription or indicate “no substitution” to the pharmacist in the case of a verbal prescription. The form(s) must be completely filled out noting the details of the adverse reaction(s) and signed by the prescriber.

Upon receipt of a “no substitution” prescription, the pharmacist will continue to:

- Clearly note on each adverse drug reaction form(s) - **“ODB NO SUBSTITUTION”**; and

- Fax or mail the completed and signed form(s) to Health Canada's Canada Vigilance Program if not already submitted by the prescriber; and
- Retain copies of the completed and signed adverse drug reaction form(s) in a readily retrievable format at the pharmacy.

Health Canada adverse drug reaction forms do not have an expiry date and serve as a permanent record.

The pharmacist will continue to be required to mail or fax the completed form(s), where it has not been submitted by the prescriber, to:

Canada Vigilance Program, Marketed Health Products Directorate, Health Canada, Postal Locator 0701E, Ottawa, Ontario K1A 0K9 Fax: 1-866-678-6789

In accordance with sections 19 and 29 of O. Reg. 201/96 made under the *Ontario Drug Benefit Act*, the dispensary is required to retain a copy of the prescription and the required Health Canada adverse drug reaction form(s) (completed and signed by the prescriber) in a readily retrievable format.

An ODB recipient with a valid "no substitution" prescription that was filled **prior** to October 1, 2015 will be permitted to renew and refill their brand therapy as directed, as long as the appropriate documentation remains on file.

If an ODB recipient chooses to exercise their personal preference for the brand therapy without trying one or more lower-cost generic drug products, pharmacists may continue to provide them with their choice and it will be the responsibility of the recipient to pay for any cost difference as per the usual process. The same will apply if the ODB recipient's prescriber does not provide the appropriate adverse reaction reporting forms to the pharmacy.

Pharmacists are encouraged to discuss alternative lower-cost treatment options, where available, with these patients and their prescribers.